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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,427	10/12/2001	Michael J. Young	ERI-113XX	9775

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STEPHEN E. REITER
FOLEY & LARDNER
P.O. BOX 80278
SAN DIEGO, CA 92138-0278

EXAMINER	
CHEN, SHIN LIN	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 02/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,427	YOUNG ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *2,16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-15 and 18-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment filed 10-26-04 has been entered. Claims 1, 4-13, 18 and 21 have been amended. Claims 1-25 are pending and claims 1, 3-15 and 18-25 are under consideration.

Applicants argue that the present invention require use of neural progenitor cells obtained from adult donors to treat dystrophic neural tissue but Gage only teaches the ability of adult neural progenitor cells to survive upon transplantation into the adult brain. The "special technical feature" of groups I and II is introducing and replacing diseased neurons with neural progenitor cells but not necessary to treat the disease. Gage teaches culturing neural progenitor cells isolated from adult rat hippocampus and transplanting said cells back into adult rat hippocampus. Further, Martinez-serrano teaches preparation of NGF-secreting CNS-derived conditionally immortalized temperature sensitive neural progenitor (CINP) cells and use said CINP cells for gene transfer of NGF to adult rat brain to rescue axotomized cholinergic neurons after transplantation into the septum. Thus, no "special technical feature" is contributed by the present invention over the prior art. The requirement is still deemed proper and is therefore again made FINAL.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 3-15 and 18-25 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for preparation of adult rat hippocampal progenitor cells

(AHPCs) isolated and cultured from adult rat hippocampus, expression of GFP in various cells in host retina as disclosed when AHPCs were injected into the vitreous or subretinal space of an eye, differentiation of the injected AHPCs into neurons with morphological characteristics suggestive of native retina cell types in mice or rats, and some behavioral recovery as measured by optokinetic nystagmas (OKN) reflex testing rats, does not reasonably provide enablement for a method of treating various dystrophic neural tissues in an animal recipient by introducing neural progenitor cells derived from various parts of central nervous system (CNS) of an adult animal donor via various administration routes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims and is repeated for the reasons set forth in the preceding Official action mailed 5-26-04. Applicant's arguments filed 10-26-04 have been fully considered but they are not persuasive.

Applicants argue that the specification provides substantial guidance for isolating and culturing neural progenitor cells, and how to use neural progenitor cells to treat dystrophic neural tissue (amendment, p. 9). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 5-26-04. Although method of isolating and culturing neural progenitor cells and method of administering the neural progenitor cells into an individual are known, there are limited sources of neural progenitor cells derived from an adult animal donor, i.e. cells isolated and cultured from the subgranular zone in the dentate gyrus of the hippocampus and the forebrain subventricular zone (SVZ). The claims encompass treating various dystrophic neural tissues in an animal recipient by introducing neural progenitor cells derived from various parts of central nervous system (CNS) of an adult animal donor via various administration

routes. There is no evidence of record that areas in the adult brain of any animal other than the disclosed dentate gyrus of hippocampus and SVZ can produce neural progenitor cells for treating numerous different dystrophic neural tissues as claimed. There are also difficulties in isolating homogenous neural progenitor cells from an adult donor. Heterogeneous cells including non-neuronal cells are the common problems in isolating neural progenitor cells from adult or neonatal mammalian nervous system.

The dystrophic neural tissues encompass damaged, injured, or diseased neural tissues derived from numerous neural diseases or disorders, including Huntigton's disease, Wilson's disease, Parkinson's disease, ALS and variants thereof, spinal cerebellar ataxia, parepheral neuropathy, retinal neuronal degeneration, Alzheimer's diseaseepilepsy, and lysosomal storage disorders etc. (see specification, pages 5-6). The specification fails to provide adequate guidance and evidence for how to isolate and culture neural progenitor cells from various parts of CNS of an adult animal donor other than hippocampus and SVZ. The specification also fails to provide adequate guidance and evidence for how to use the neural progenitor cells derived from various brain tissues, which could have heterogeneous cell populations, to treat numerous dystrophic neural tissues derived from various neural diseases or disorders so as to provide therapeutic effect in the animal recipient either allogeneic, syngeneic, or of different species via various administration routes, such as intravenous injection, intraperitoneal injection, intramuscular injection, oral administration etc. Different administration routes of the neural progenitor cells to dystrophic neural tissue in an animal recipient would result in different effect in said animal. Thus, one skilled in the art at the time of the invention would not know how to use the claimed neural progenitor cells to treat dystrophic neural tissues derived from numerous neuronal

diseases and disorders such that therapeutic effect could be obtained in vivo via various administration routes, and it would have required undue experimentation for one skilled in the art at the time of the invention to practice over the full scope of the invention claimed.

Conclusion

No claim is allowed.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.

SHIN-LIN CHEN
PRIMARY EXAMINER